

K103349

Section 5. 510(k) Summary

Safety and Effectiveness Data Summary

JAN - 7 2011

Prepared By: Pluromed Inc.
25-H Olympia Avenue
Woburn, MA 01801

Telephone Number: 781-932-0574
Fax Number: 419-828-6350

Contact Person: James Wilkie
jwilkie@pluromed.com

Proprietary Name: 3F BackStop™ Catheter
Classification Name: Urological Catheters and Accessories
Common Name: Urological Catheter

Classification: Class II
Regulation Number: 876.5130
Product Code: 78 KOD

Indications for Use The Pluromed 3F BackStop™ Catheter is indicated for use by physicians for facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the injection of gels, such as BackStop™, or fluid into the urinary tract.

Performance Standards: Recognition Number 14-193: AAMI / ANSI / ISO 11607-1:2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, 3ed.

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Recognition Number 2-98: AAMI / ANSI / ISO 10993-1:2009(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing.

Recognition Number 14-224: AAMI / ANSI / ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.

Recognition Number 14-225: AAMI / ANSI / ISO 11137-2:2006, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

Substantial Equivalence: Pluromed BackStop™ Catheter, K090270.

Description of Device: The Pluromed 3F BackStop™ Catheter is a 100 cm, 3F, single lumen, radiopaque catheter that facilitates access to the urinary tract. The catheter may be inserted over a guidewire or through the working channel of an ureteroscope and is advanced through the urinary tract to the desired location in the ureter. Once in place fluid or gels, such as BackStop™, may be injected via the catheter.

The device is a single lumen catheter with a stainless steel braid and a standard female luer lock hub on the proximal end.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. James Wilkie
Vice President, Operations
Pluromed, Inc.
25-H Olympia Avenue
WOBURN MA 01801

JAN - 7 2011

Re: K103349

Trade/Device Name: 3F BackStop Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KOD
Dated: November 12, 2010
Received: November 16, 2010

Dear Mr. Wilkie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

K103349

Section 4. Indications for Use

510(k) Number (if known):

K103349

Device Name: 3F BackStop Catheter

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Indications for Use:

The 3F BackStop Catheter is indicated for use by physicians for facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the injection of gels, such as BackStop™, or fluid into the urinary tract.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

AND/OR

Over the Counter Use

(21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

Angela M. Wray
(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and
Urological Devices

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